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10/078,678	02/21/2002	Yoji Sakagami	026350-071	4782

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EXAMINER

KALLIS, RUSSELL

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 08/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/078,678

Applicant(s)

SAKAGAMI ET AL.

Examiner

Russell Kallis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1,7-12 and 17-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-6 and 13-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 10/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION*****Election/Restrictions***

Applicant's election with traverse of Group III, Claims 2-6 and 13-16 in the reply filed on June 23, 2004 is acknowledged. The traversal is on the ground(s) that since the polynucleotides of Groups I and II encode the polypeptides of Groups III and IV the Groups are related and the Groups should be examined together, and that since the Groups pertain to precursor polypeptides of phytosulfokine all the Groups are related and should be examined together. This is not found persuasive because the polynucleotides and transformed cells and plants of Groups III and IV and the polypeptides of Groups I and II have different structure, function and chemical composition and would require different searches. Applicant also adds that searching the additional sequences would not constitute a serious burden upon the office emphasizing that 'normally ten sequences constitutes a reasonable number', and are permitted per MPEP 803.04. This is not found persuasive because sequences of Groups I-IV are drawn to unique DNA and protein compositions requiring a different search. The prior indication, in 1996, that up to ten sequences were permissible was meant to apply to EST sequences, rather than promoters or coding sequences. Furthermore, since 1996 resources at the Patent office have changed, and the examination and search of more than one sequence would pose an undue burden. Finally, the MPEP also recites in 803.04 that "up to ten independent and distinct inventions can be examined", and thus one sequence constitutes "up to ten".

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-20 are pending. Claims 1, 7-12 and 17-20 are withdrawn. Claims 2-6 and 13-16 are examined.

### ***Claim Objections***

Claims 2 and 3 objected to because of the following informalities: Claims 2 and 3 depend from non-elected Claim 1. Appropriate correction is required. In the interest of compact prosecution, Claims 2 and 3 will be examined with respect to the limitations of non-elected Claim 1.

### ***Sequence Rules***

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth: Figures 1, 2, 5, 6 and 7 require sequence identifiers and on page 6 of the specification.

§ 1.821 Nucleotide and/or amino acid sequence disclosures in patent applications;

(d) Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.

Applicant must amend the claims, specification, and/or drawings to insert sequence identifiers.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-6 and 13-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

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which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant broadly claims a gene encoding a precursor polypeptide of phytosulfokine derived from *Arabidopsis* that hybridizes to SEQ ID NO: 2 under a stringent condition or has more than 70% sequence identity with SEQ ID NO: 2; a method of promoting cell proliferation in a plant cell using said sequences, and plant cells transformed thereof.

Applicant describes SEQ ID NO: 2 encoding SEQ ID NO: 1 and incorporates through reference the cDNA encoding phytosulokine from rice known in the art, and describes the conserved PSK- $\alpha$  domain common to the *Arabidopsis* and rice sequences.

Applicant does not describe a gene encoding a precursor polypeptide of phytosulfokine derived from *Arabidopsis* having more than 70% sequence identity to SEQ ID NO: 2, a gene encoding a precursor polypeptide of phytosulfokine derived from *Arabidopsis* having more than 70% sequence identity to SEQ ID NO: 1, or a nucleic acid sequence that hybridizes to SEQ ID NO: 2 under a stringent condition.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. The court stated that, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicants fail to describe a representative number of genes encoding a precursor polypeptide of phytosulfokine derived from *Arabidopsis* falling within the scope of the claimed genus of genes encoding a precursor polypeptide of phytosulfokine derived from *Arabidopsis* having more than 70% sequence identity to SEQ ID NO: 2, genes encoding a precursor polypeptide of phytosulfokine derived from *Arabidopsis* having more than 70% sequence identity to SEQ ID NO: 1, and a nucleic acid sequences that hybridizes to SEQ ID NO: 2 under a stringent condition. Applicants only describe a single cDNA (SEQ ID NO: 2) encoding (SEQ ID NO: 1). Furthermore, Applicants fail to describe structural features common to members of the claimed genus of genes. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*.

Sequences that hybridize with SEQ ID NO: 2, or have more than 70% sequence identity to SEQ ID NO: 2, or genes that encode a protein sequence having more than 70% sequence identity to SEQ ID NO: 1 encompass naturally occurring allelic variants, mutants of a phytosulfokine protein, as well as sequences encoding proteins having no phytosulfokine activity, of which Applicant is not in possession. Accordingly, the specification fails to provide an adequate written description to support the genus of polynucleotides encompassed by the hybridization language or percent identity language as set forth in the claims. (See Written Description guidelines published in Federal Register/Vol. 66, No.4/Friday, January 5, 2001/Notices: p.1099-1111).

Claims 2-6 and 13-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide of SEQ ID NO: 2 encoding a phytosulfokine of SEQ ID NO: 1 from *Arabidopsis* and increased proliferation in *Arabidopsis* or dicot cells transformed with SEQ ID NO: 2, does not

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reasonably provide enablement for polynucleotides encoding a phytosulfokine derived from *Arabidopsis* having more than 70% sequence identity to SEQ ID NO: 2 or that hybridize to SEQ ID NO: 2 under a stringent condition encoding a phytosulfokine for promoting cell proliferation in a transformed monocot plant cell. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

Applicant broadly claims a gene encoding a precursor polypeptide of phytosulfokine derived from *Arabidopsis* that hybridizes to SEQ ID NO: 2 under a stringent condition or has more than 70% sequence identity with SEQ ID NO: 2; a method of promoting cell proliferation in a plant cell using said sequences, and plant cells transformed thereof.

Applicant teaches isolation of *Arabidopsis* phytosulfokine cDNA clones of SEQ ID NO: 2 and SEQ ID NO: 4 encoding SEQ ID NO: 1 and SEQ ID NO: 3, by screening an *Arabidopsis* cDNA library with a probe made by PCR amplification of the cDNA

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library using degenerate oligo primers of the 3' conserved PSK- $\alpha$  domain (pages 15-16), and increased cell division in *Arabidopsis* cells transformed with SEQ ID NO: 2 and 4.

Applicant does not teach polynucleotides encoding a phytosulfokine derived from *Arabidopsis* having more than 70% sequence identity to SEQ ID NO: 2 or that hybridize to SEQ ID NO: 2 under a stringent condition promoting cell proliferation in a transformed plant cell.

The unpredictability in isolating and identification of genes from any species of plant encoding a phytosulfokine having more than 70% identity to the *Arabidopsis* phytosulfokine gene of SEQ ID NO: 2 or that hybridize to SEQ ID NO: 2 arises because the use of heterologous probes is excluded due to the significant difference in sequence identity for polynucleotides encoding phytosulfokines across the species. Researchers were unable to isolate the *Arabidopsis* AtPSK2 clone of SEQ ID NO: 2 using the rice PSK DNA as a probe because it would not hybridize to the *Arabidopsis* cDNA, and the *Arabidopsis* clones AtPSK2 and AtPSK3 did not cross hybridize either, and therefore it is unlikely that any phytosulfokine encoding gene either from *Arabidopsis* or from another species would hybridize to SEQ ID NO: 2 from *Arabidopsis* (Yang H. et al. Plant Physiology, November 2001, Vol. 127, pp. 842-851; see page 847, column 1, lines 5-7; and Applicant's specification on page 15, lines 22-23). Further, genes that have 70% sequence identity to SEQ ID NO: 2 embraces variants to the conserved PSK domain that is highly conserved and would most likely not tolerate sequence changes because it is required for specific protein receptor interactions. Researchers showed that the overexpression of an LLR receptor enhanced cellular response to phytosulfokine ligand (Matsubayashi Y. et al. Science, 24 May 2002; Vol. 296, pp. 1470-1472; Abstract 1-10

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and page 1472, column 2, lines 16-24). Moreover, any gene derived from *Arabidopsis* and still possessing phytosulfokine activity would not function in monocot cells.

Researchers did not observe cross feeding effects for phytosulfokines between heterospecific cells at the level of dicot and monocot (Matsubayashi Y. et al., PNAS, July 1996; Vol. 9, pp. 7623-7627; see page 7627 column 1, 2<sup>nd</sup> full paragraph).

Given the lack of guidance in the instant specification, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through a multitude of non-exemplified sequences that have more than 70 % sequence identity or hybridize to SEQ ID NO: 2 transforming plant cells therewith, in order to identify those polynucleotides that when expressed produce plant cells with an increased rate of cell division or cell proliferation.

Therefore, given the breadth of the claims; the lack of guidance and working examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled throughout the broad scope of the claims.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 2-4 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 2-4 are drawn to a gene encoding a precursor polypeptide of phytosulfokine derived from *Arabidopsis*. The claimed inventions encompasses genes that are not isolated or purified from a plant by the hand of

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man, and thus are a product of nature and not one of the five classes of patentable subject matter. See *American Wood v. Fiber Distintegrating Co.*, 90 U.S. 566 (1974), *American Fruit Growers v. Brogdex Co.*, 283 U.S. 2 (1931), *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 33 U.S. 127 (1948), *Diamond v. Chakrabarty*, 206 USPQ 193 (1980).

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 4-6 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,403,864. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of patent 6,403,864, in view of the specification, render the claims of the instant application obvious.

The claims of the instant application are broadly drawn to a gene consisting of a sequence of unspecified source, length and identity that hybridizes with the polynucleotide sequence of SEQ ID NO: 2 under conditions of unspecified stringency encoding a phytosulfokine precursor polypeptide; a method to promote plant cell proliferation by transformation with said polynucleotide, and transformed plant cells.

Claims 1-8 of U.S. Patent 6,403,864 teach a purified DNA encoding a precursor polypeptide of phytosulfokine of SEQ ID NO: 1; a polynucleotide of SEQ ID NO: 2 encoding SEQID NO: 1; methods of promoting proliferation or growth in a rice cell transformed with said polynucleotides; and plant cells comprising said polynucleotides encoding a precursor polypeptide of phytosulfokine.

Claims 1-8 do not teach SEQ ID NO: 2 from *Arabidopsis* encoding a precursor polypeptide of SEQ ID NO: 1.

The specification of U.S. Patent 6,403,864 teach the detection of rice phytosulfokine homologs in *Arabidopsis*, Asparagus, carrot and Zinnia by southern hybridization with a rice phytosulfokine probe (see Figure 11 and in column 7); that the gene of the invention includes a gene that hybridizes with the polynucleotide sequence from rice disclosed as SEQ ID NO: 2 (see column 2, lines 37-40); and the gene disclosed in the patent can be incorporated into various plants (see column 2, lines 50-64).

It would have been obvious to modify the invention taught by the claims of U.S. Patent 6,403,864 to include the sequences that hybridize with the polynucleotide sequence of SEQ ID NO: 2 from *Arabidopsis*, of the instant application, under conditions of unspecified stringency, and encode a precursor polypeptide of phytosulfokine. One of ordinary skill in the art would have been motivated to fashion a heterologous probe using a phytosulfokine sequence to identify phytosulfokine homologs and would have a reasonable expectation of success of identifying phytosulfokine homologs from other plant species using a heterologous probe.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Yang H. *et al.* Plant Molecular Biology, November 2000, Vol. 635, pp.635-647.

The claims are drawn to a phytosulfokine encoding DNA sequence of unspecified source, identity, and length that hybridize, under conditions of unspecified stringency, to the polynucleotide encoding a phytosulfokine from *Arabidopsis* of SEQ ID NO: 2; a method of promoting proliferation of plant cells transformed with said sequence, and a plant cell transformed therewith.

Yang teaches a rice phytosulfokine cDNA transformed into cultured rice cells having a greater rate of cell proliferation compared to wild type rice cells (see page 636, column 1 beginning with the last paragraph to column 2 end of first paragraph; page 640, page 642 in figure 5; page 642 column 2, and page 644 in column 1 first full paragraph), and thus the reference teaches all the limitations of Claims 4-6.

All claims are rejected.

Claims 2-3 and 13-16 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest an isolated polynucleotide of SEQ ID NO: 2 encoding a phytosulfokine of SEQ ID NO: 1, a method of promoting cell proliferation in plant cells transformed with SEQ ID NO: 2, and plants cells transformed thereby.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Russell Kallis*

Russell Kallis Ph.D.  
August 4, 2004